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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,840	03/01/2006	Joachim Schmitt	SCHM3001/REF	8834
23364 7590 02/21/2008 BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 02/21/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/538,840

Applicant(s)

SCHMITT ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-31, 33-36 and 38-48 is/are rejected.
- 7) ☒ Claim(s) 32, 37 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' Response to Office Action, received 26 November 2007, is acknowledged. Claims 1-15, 17, 18, 23, 25, and 26 have been canceled. New claims 27-48 have been added.
2. Claims 27-48 are pending and under consideration.

**Objections/Rejections Withdrawn/Moot**

3. The objection to claim 2 is moot in light of the cancelation of the claim.
4. The objection to claim 4 is moot in light of the cancelation of the claim.
5. The objection to claim 5 is moot in light of the cancelation of the claim.
6. The objection to claim 7 is moot in light of the cancelation of the claim.
7. The objection to claim 8 is moot in light of the cancelation of the claim.
8. The objection to claim 9 is moot in light of the cancelation of the claim.
9. The objection to claim 17 is moot in light of the cancelation of the claim.
10. The objection to claim 18 is moot in light of the cancelation of the claim.
11. The rejection of claims 1-5 under 35 U.S.C. 101, non-statutory subject matter, is moot in light of the cancelation of the claims.
12. The rejection of claims 6-9 under 35 U.S.C. 101, non-statutory subject matter, is moot in light of the cancelation of the claims.
13. The rejection of claims 3, 6, 7, 10-15, 17, 18, and 23 under 35 U.S.C. 112, second paragraph for "in accordance with", is moot in light of the cancelation of the claims.
14. The rejection of claims 3 and 10 under 35 U.S.C. 112, second paragraph for "derived", is moot in light of the cancelation of the claims.
15. The rejection of claim 6 under 35 U.S.C. 112, second paragraph for "comprises", is moot in light of the cancelation of the claim.

16. The rejection of claim 26 under 35 U.S.C. 112, second paragraph for "pharmaceutical composition", is moot in light of the cancelation of the claim.

17. The rejection of claims 6, 7, 12, 17, 18, 23, and 26 under 35 U.S.C. 112, second paragraph for "functional equivalents", is moot in light of the cancelation of the claims.

18. The rejection of claims 10 and 11 under 35 U.S.C. 112, second paragraph for "material", is moot in light of the cancelation of the claims.

19. The rejection of claim 25 under 35 U.S.C. 112, second paragraph for "if required", is moot in light of the cancelation of the claim.

20. The objection to Figure 1 is withdrawn in light of the corrected drawing.

21. The objection to Figure 3 is withdrawn in light of the corrected drawing.

#### **Claim Objections**

22. Claim 32 is objected to because of the following: there should be either "and" or "or" separating the two listed sequences. Appropriate correction is required.

23. Claim 37 is objected to because of the following: "of either claims" should be "of either claim". Appropriate correction is required.

24. Claim 45 is objected to because of the following: only the name of the organism should be italics. Appropriate correction is required.

#### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

25. Newly added claim 38 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim reads on a product of nature, i.e., nonisolated polynucleotides which read on whole bacterial polynucleotides within live *T. congolense*.

**Claim Rejections - 35 USC § 112**

26. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

27. Claims 27-31, 35, 42-44, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly added claim 27 recites that the sequences are "derived" from the polynucleotides. The specification does not define the term "derived", therefore it is unclear what the metes and bounds of this term encompasses.

Also, claim 27 recites that the isolated polynucleotide comprises a nucleic acid sequence "of" SEQ ID NO:1 or 3. Because of the recitation, sequence "of" a sequence, it is unclear if the claimed polynucleotide comprises the entire sequence of SEQ ID NO:1 or 3, or if the claimed polynucleotide comprises a subsequence of SEQ ID NO:1 or 3.

Claims 28-31, 35, 42-44, and 47 depend from claim 27, but do not clarify the issues.

28. Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In newly added claims 29 and 30, the phrase "stringent conditions" is vague and indefinite because hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration, and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require a knowledge of these specific parameters. The claims do not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth in the claims the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure.

29. Claims 31, 42-44, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly added claim is drawn to an isolated polypeptide which is coded by a polynucleotide which "comprises" a nucleic acid sequence of claim 27. The use of the open language, i.e., "comprises" allows for any number of unknown nucleotide residues on either end of a nucleic acid sequence of claim 27. Thus, a polypeptide encoded by said polynucleotide may be encoded by the unknown regions and therefore the polypeptide sequence is unknown.

Claims 42-44 and 47 depend from claim 31, but do not clarify the issue.

30. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, because claim 33 recites the limitation "The isolated trans-sialidase 1 (TS1) of claim 32" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 32 does not recite either TS1 Or "trans-sialidase 1".

31. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, because the claim recites the limitation "The isolated trans-sialidase 2 (TS2) of claim 32" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 32 does not recite either TS2 Or "trans-sialidase 2".

32. Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to "The isolated trans-sialidase" of claim 32, characterized by at least one of 8 characteristics of which one is drawn to a nucleotide sequence and another drawn to an amino acid sequence. It is unclear what is being claimed, i.e., the protein or the DNA. It is recommended that if the protein is being claimed, then the wording for claim 33 should be "encoded by nucleotide sequence SEQ ID NO:1" and "consisting of SEQ ID NO:2". It is recommended that if the protein is being claimed, then the wording for claim 34 should be "encoded by nucleotide sequence SEQ ID NO:3" and "consisting of SEQ ID NO:4".

33. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "The isolated polynucleotides and trans-sialidases of claim 27". However, claim 27 is only drawn to isolated polynucleotides. Therefore, it is unclear what is being claimed, i.e., DNA or protein.

34. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites "The isolated polynucleotides, polypeptides, oligonucleotides, and trans-sialidases of claim 27". However, claim 27 is only drawn to isolated polynucleotides. Therefore, it is unclear what is being claimed, i.e., DNA, polypeptides, or protein.

35. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a preamble and 3 components (a), (b) and (c) but does not provide an relationship between the preamble and the components such as "comprising", "consisting of" or other relationship indicator. Therefore it is unclear what is being claimed.

36. Claims 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is drawn to a method for isolation of an enzyme from a culture supernatant by means of ion exchange chromatography "with the help of" a salt gradient. It is unclear what is meant by the phrase "with the help of". Claim 46 depends from claim 45, but does not clarify the issue.

37. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by a "gene-therapeutical" composition or "gene-therapeutically compatible" carrier.



38. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what are the metes and bounds of "an effective amount" because there is no recitation of what the amount is effective against, nor what levels are deemed effective.

39. Claims 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

### Conclusion

40. No claims are allowed.

41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

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272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

February 13, 2008